**Remarks**

The Office Action dated March 31, 2005 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

While written support for the claims amendments can be found throughout the specification, specific written support can be found, for example, at page 12 lines 15 to 24. Applicants therefore submit that no new subject matter has been added by the amendments to the claims and that they are fully supported by the text of the specification.

**Summary of Office Action**

1. Claims 14 to 34 were rejected under 35 U.S.C. 101 and 112, first paragraph allegedly because the claimed invention is allegedly not supported either by a specific and substantial asserted utility or by a well established utility, and because the specification allegedly does not adequately disclose to the skilled person how to use the claimed invention.

2. Claims 14, 17 and 26 to 34 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 14, 17 and 26 to 34 were rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Smith *et al.* (U.S. Patent 5,972,624).

**Rejection under 35 U.S.C. 101**

The Examiner has rejected claims 14 to 34 because the claimed invention is allegedly not supported either by a specific and substantial asserted utility or by a well established utility. The Examiner has also rejected claims 14 to 34 under 35 U.S.C. 112, first paragraph, because the specification allegedly does not adequately disclose to the skilled person how to use the claimed invention.

Applicants respectfully disagree with these rejections and submit that the claimed nucleic acids have a specific, substantial and credible utility as "minus targets" in counter-screens in identifying compounds that specifically interact with target galanin receptors.

The specification discloses (see page 26, lines 1 to 17) that in order to find compounds that interact with receptor A, it is necessary to ensure not only that the compounds specifically interact with receptor A (the "plus target") and produce the desired pharmacological effect through receptor A, but also to determine that the compounds do not act through receptors B, C, D, etc. (the "minus target"). The present invention identifies GPR54 as the closest known relative of the galanin receptors. The claimed nucleic acid molecules display nucleotide sequence identity to the genes encoding the GALR1, GALR2 and GALR3 receptors (see page 9, lines 5 to 9 and Figure 8). Nucleic acids encoding GPR54 also display an expression pattern which substantially overlaps with the expression pattern for galanin receptors (page 10, lines 12 to 21 and Figure 7). However, the GPR54 gene product does not bind the endogenous ligand (*i.e.*, galanin) for galanin receptors (see page 10, lines 22 to 31).

The nucleic acids encoding the GPR54 gene product therefore serve a specific, substantial and credible utility as a minus target in methods to identify compounds which bind to and modulate galanin receptors. The asserted utility is specific because of its relation to galanin receptors and not any receptor protein. The asserted utility is substantial and credible because methods to identify compounds which bind to a drug target have long been held to represent a useful invention and thus, satisfy the utility requirement (see *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996)). It is therefore submitted based upon the above remarks that the presently claimed invention meets the requirements of 35 U.S.C. 101 and 112, first paragraph, and withdrawal of the rejection is requested.

**Rejection under 35 U.S.C. 112**

The Examiner has rejected claims 14, 17 and 26 to 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The claims encompass the term "high stringency" which is allegedly a relative term whose metes and bounds are not clear with regard to hybridization.

Without acquiescing to the merits of the rejection and solely for the purpose of advancing prosecution, the claims have been amended to explicitly recite the hybridization conditions disclosed in the application as filed (see, *e.g.*, page 12, lines 15 to 24). In view of these amendments, Applicants submit that the rejection is moot and withdrawal of this rejection is requested.

**Rejection under 35 U.S.C. 102**

The Examiner has rejected claims 14, 17 and 26 to 34 under 35 U.S.C. 102(e) as being anticipated by Smith *et al.* (U.S. Patent 5,972,624). The Examiner has said that Smith discloses a nucleic acid encoding galanin receptor as well as vectors and host cells comprising the nucleic acid and also teaches methods of producing the protein using the host cell.

Without acquiescing to the merits of the rejection and solely for the purpose of advancing prosecution, all independent claims have been amended to expressly recite a set of hybridization conditions of high strigency under which the claimed nucleic acid would specifically hybridize.

Applicants also bring to the attention of the Examiner that the cited reference describes the GALR2 receptor. The Examiner has indicated that the nucleic acid sequence encoding this GALR2 receptor has a very low degree of identity to the claimed nucleic acids (see page 3 of the Office Action dated March 31, 2005). In view of these remarks and the claim amendments contained herein, Applicants submit that the nucleic acid sequence disclosed in the cited reference would not specifically hybridize to the presently claimed nucleic acid comprising SEQ ID NO:1 under the recited stringency conditions. The ability of two sequences to hybridize is dependent on the level of sequence identity, and the level of identity between the sequence of Smith *et al.* and SEQ ID NO: 1 is too low to allow hybridization under the recited conditions. Withdrawal of the rejection is respectfully requested.

Applicants respectfully request reconsideration of the subject application in view of the above remarks and withdrawal of the rejections. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner believe it to be useful, an interview with the Examiner is respectfully requested in order to discuss the foregoing claims.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted
**Morgan, Lewis & Bockius LLP**

Dated: **August 1, 2005**
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